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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,546	04/25/2000	ELLIOTT BENNETT-GUERRERO	08213/007001	6875

7590

09/24/2003

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 09/24/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,546

Applicant(s)

BENNETT-GUERRERO ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003, 4 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44,55-59,61-64,66-68,73-76,78-88,93,94 and 97-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44,55-59,61-64,66-68,73-76,78-88,93,94,99,100 is/are allowed.
- 6) ☒ Claim(s) 97 and 98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 26.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25July2003, has been entered.

The Declaration of Dr. Bennett-Guerrero, paper#23, received 25July2003 has not been considered as the Declaration has not been signed.

2. The Declaration of Dr. Bennett-Guerrero, received 4August2003, paper#25, has been entered.

3. The Supplemental Information Disclosure Statement, received 4August2003, paper#26, has been entered.

4. Claims 44, 55-59, 61-64, 66-68, 73-76, 78-88, 93, 94, and 97-100 are pending and under consideration.

Rejections Withdrawn

5. The rejection of claims 44, 55-59, 61-64, 66-68, 73-76, 78-88, 93, 94, 99, and 100 under 35 U.S.C. 112, first paragraph, scope of enablement for treatment of animals, is maintained for reasons of record.

Applicants request clarification from the examiner as to the distinction between immunization and treatment by administration.

Immunization, by definition, denotes the induction of any immune response in a subject. This immune response may consist of antibody or cell mediated immunity

Art Unit: 1645

which has no protective aspects against a disease state. Treatment by administration denotes that whatever is administered to a subject results in an effect on the disease state or condition, i.e., amelioration or complete eradication of symptoms or the disease. The instant claims are drawn to "A method of reducing adverse effects of endotoxin" by "administering" "a composition comprising rough, complete-core lipopolysaccharide". As stated in the original rejection, the instant specification contains insufficient guidance/examples for the scope of the claims, i.e., inducing some sort of effect in a host which reduces the adverse effects of endotoxin. Guidance needed to support the claims comprises dosage, timing of administration, route of administration, composition of material administered and data which indicates that such administration does indeed reduce the adverse effects of endotoxin in a subject. The instant specification does not provide such information, merely *in vitro* binding assays and induction of antibodies.

Applicants support their arguments that the claims are enabled for treatment of animals with the submission of a Declaration by Dr. Bennett-Guerrero. The Declaration contains examples of treating subjects with the claimed compositions, with the result being survival of the subjects following a challenge with LPS.

The examiner has considered the Declaration by Dr. Bennett-Guerrero, and finds the examples sufficient for supporting the claimed methods.

Rejections Maintained

6. The rejection of claims 97 and 98 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is maintained for reasons of record.

Applicants argue that the statute of 35 U.S.C. 112, second paragraph, only requires that the claims have reasonably definite metes and bounds and that those

Art Unit: 1645

skilled in the art must know that the claim covers and what it does not. Applicants argue that the Examiner is requiring particular proprietary software and commercially available apparatus.

The examiner has considered applicants' arguments, but does not find them persuasive. While the examiner is not requiring any particular proprietary software and commercially available apparatus, the claims are incomplete in that just staining with periodic acid/Schiff base does not quantitate the amount of LPS, but merely indicates whether LPS is present or not present. Some type of quantitation procedures is necessary to complete the claimed methods. For example, there is no recitation of any controls for comparison of staining of liposomes and therefore no way of determining any quantities in the unknown samples.

Conclusion

7. Claims 97 and 98 are rejected. Claims 44, 55-59, 61-64, 66-68, 73-76, 78-88, 93, 94, 99, and 100 appear to be allowable over the prior art of record.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306.

Art Unit: 1645

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER

Art Unit 1645

September 23, 2003